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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,160	07/09/2001	Jack V. Smith		7063

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EXAMINER

CROSS, LATOYA I

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/901,160

Applicant(s)

SMITH, JACK V.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9-26-03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed on September 26, 2003 and entered as Paper No. 4. Claims 1, 2, and 5 are pending. Claims 3 and 4 have been cancelled.

Drawings

1. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect may be deferred until after the examiner has considered the proposed drawing correction. Failure to timely submit the proposed drawing correction will result in the abandonment of the application. Reference characters '13' and '14' both denote the shaft.

Claim Observations

- Claim 1 contains the phrases "said last means" and "said shaft chamber" which there is insufficient antecedent basis.

- Claim 5 is directed to a method for collecting and analyzing a fluid specimen. The first step of the method recites "containing means for collecting the said specimen". This is not in fact a method step. It is suggested that Applicants amend the claims to be more consistent with the method described at page 6 of the specification. It is also suggested, with respect to claim 5, that the limitation of "without the use of plungers, plenums and tilting of the said container means" be amended to recite "wherein depressing the activation means does not require the use of plungers, plenums or tilting of the said container means", so that the limitation is not construed in the context of the recording step.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Guirguis et al.

Guirguis et al teach a device for both collecting and testing a fluid specimen, in particular urine. With respect to claim 1, the device comprises a specimen container (15) having a collection chamber (40) for collecting a fluid specimen and an opening (25) allowing fluid to be placed into the container. The device also includes a cap (20) for sealing the container. A test chamber (80) having a test agent (95) is equivalent to Applicants' claimed assay means (col. 5, line 60 – col. 6, line 3). The test agent (95) is preferably a test strip such as an immunochromatographic test strip (col. 6, lines 3-6). At col. 6, lines 63-67, Guirguis et al teach that the device may include test strips for detecting drugs of abuse or for performing multiple tests for multiple analytes. At col. 7, lines 1-6, Guirguis et al teach that at least two test strips, preferably five or six test strips may be present in the device to test for different analytes. Figures 1-3 show the test chamber being position on an outside wall of the device, as recited in claim 3. Further with respect to claim 1, Guirguis et al teach activating the assay means by penetrating a frangible bottom wall (75) of the isolation chamber (65) with a fluid releasing element (100) which is preferably in the form of a spike (102), which is equivalent to

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Applicant's claimed shaft means (col. 7, lines 14-24). With respect to claim 2, Guirguis et al teach that fluid communication between the isolation chamber and the test chamber holding the test strips is facilitated by a fluid flow path (32). This fluid flow path is equivalent to Applicant's claimed lateral flow means. With respect to the method of claim 4, Guirguis et al teach, collecting a sample into the collection chamber (40) of the device, sealing the device with the lid (20), which activates the fluid releasing element (100) causing fluid to flow via the fluid flow path (32) into the test chamber (80), where the fluid contacts reagents on the test strips to analyze the constituents of the fluid. See col. 8, lines 12-42.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(e) in view of the teachings of Guirguis et al.

Response to Arguments

4. Applicant's arguments filed September 26, 2003 have been fully considered but they are not persuasive. In response to the rejection over Guirguis et al, Applicants argue that the Guirguis et al patent requires limitations that are not required in the instant application. In response, the instant claims use "comprising" language, which is open-ended language meaning that additional, unrecited elements are not excluded. See MPEP 2111.03. Thus, although Guirguis et al may require additional elements not recited by Applicant, the claims are still anticipated, due to the open-ended language. Also, it should be noted that Applicants contend that a first and second chamber, releasing element and lid are required by Guirguis et al, but not required in the instant application. The Examiner disagrees. The first and second chamber, taught by Guirguis, is equivalent to Applicant's claimed container means and shaft

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chamber means. The lid in Guirguis et al is equivalent to Applicants' claimed cap means. The releasing element in Guirguis is equivalent to Applicants' claimed activating means.

Applicants further argue that the limitation of "without the use of plungers, plenums, and tilting of the said container", distinguishes the Guirguis et al from the instant invention. Applicants contend that the instant device does not require a spike, such as taught by Guirguis et al. It is the opinion of the examiner that the releasing means of Guirguis is no different than the shaft means instantly claimed by Applicants. In the instant specification, page 10, Applicants discuss what they intend the shaft means to be. Specifically, Applicants state that the shaft means is a pointed element recessed into the wall of the container. Depression of the shaft perforates an inner frangible wall of the container allowing fluid to come into contact with assay strips present in the bottom of the container. Applicants attention is turned to Guirguis et al, column 8, lines 26-36, where the reference teaches that pressing the lid onto the container causes the fluid releasing element to be driven through the frangible bottom wall directing fluid sample to the test chamber containing assay strips. Similarly to Applicant's claims, the releasing means (activation means) is depressed by the lid, causing the frangible wall to be perforated and resulting in the sample fluid being allowed to contact the assay strips.

For these reasons, the claims are deemed to be anticipated and the rejection is being maintained.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. The Examiner is scheduled to move to a new site on December 17, 2003. If attempts at the above number are unsuccessful, Applicants should try to contact the examiner at (571) 272-1256.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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December 11, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700